NOVAVAX INC
Form 8-K
March 15, 2005

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): March 14, 2005

Novavax, Inc.

(Exact name of registrant as specified in its charter)

Delaware	0-26770	22-2816046
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)
508 Lapp Road, Malvern, Pennsylvania		19355
(Address of principal executive offices)		(Zip Code)

Registrant s telephone number, including area code: 484-913-1200

Not Applicable

Former name or former address, if changed since last report

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

[ ] Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
[ ] Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
[ ] Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
[ ] Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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Item 2.02. Results of Operations and Financial Condition.

FOR IMMEDIATE RELEASE
NASDAQ symbol: NVAX

NOVAVAX ANNOUNCES FOURTH QUARTER AND FISCAL 2004 RESULTS

Malvern, PA, March 14, 2005 - Novavax, Inc., (Nasdaq: NVAX) a specialty biopharmaceutical company, today announced financial results for the fourth quarter and 2004 fiscal year.

Highlights of 2004
• Launched ESTRASORB®, a topical estrogen-therapy replacement product
• Negotiated favorable terms to terminate the King Pharmaceutical agreements and concurrently raised gross proceeds of $40 million with a net cash increase of $23 million and reduced the debt by $5 million
• Completed and validated a FDA compliant manufacturing facility
• Recruited new senior leadership for the drug delivery and vaccine technology development programs, manufacturing and marketing
• Implemented a facilities plan to reduce the number of facilities and consolidate drug delivery business in greater Philadelphia
• Formulated 5 new micellar nanoparticle products
• Successfully implemented Sarbanes-Oxley 404

"Novavax has taken a series of necessary steps in 2004 to transition itself for long term growth and sustainability. These steps included the building of a talented organization, implementation of a strategy to capitalize on micellar nanoparticle (MNP) technology as a delivery system to a wide range of pharmaceuticals, and the commercialization of our first internally developed pharmaceutical product, ESTRASORB," said Nelson M. Sims, President and CEO, Novavax, Inc. "It is clear that our efforts to commercialize ESTRASORB have not met our initial sales expectations. However, based on market research we continue to believe in the potential of ESTRASORB and that the product would benefit from a marketing partner with the necessary financial resources, market presence, and a commitment to direct-to-consumer marketing support. The completion of such a partner agreement is management's primary focus to enable ESTRASORB to achieve its full potential."

Financial Results
For the fourth quarter ended December 31, 2004, the company had a net loss of $10.3 million, or ($0.26) per share, compared to a net loss of $3.1 million, or ($0.10) per share for the quarter ended December 31, 2003. Net loss for the year ended December 31, 2004, was $25.9 million, or ($0.70) per share compared to a loss of $17.3 million, or ($0.58) per share for the prior year period. The net loss of $25.9 million for the year ended December 31, 2004, includes a one-time gain on the redemption of debt of $11.2 million.

Total revenues for the quarter were $2.0 million compared to fourth quarter 2003 revenues of $4.0 million. For the year ended December 31, 2004, revenues were $8.3 million, compared to revenues of $11.8 million for the year ended December 31, 2003.

Product sales for the three-month period ended December 31, 2004, were $2.2 million compared to $3.7 million for the same three month period in 2003. The three-month period ended December 31, 2003 benefited from the introduction and initial stocking of two new prenatal vitamin products. Net product sales for the 2004 fiscal year were $6.4 million compared to $10.2 million in the 2003 fiscal year. The 2004 product sales were negatively impacted by generic competition of the prenatal vitamin line. The 2004 product sales also reflect the $1.3 million non-recurring reserve for product returns announced earlier in the third quarter of 2004. Total net ESTRASORB sales for the 2004 fiscal year after the June launch were $1.8 million. For the 2004 fiscal year contract research and development revenue rose 34% to $1.7 million compared to 2003.

Cost of sales in the quarter was $1.4 million compared to $0.7 million for the same three month period in 2003 due to higher manufacturing costs related to ESTRASORB. Cost of sales for the year ended December 31, 2004 were $3.5 million compared to $2.1 million in 2003. The change was primarily due to the launch and sale of ESTRASORB in the second quarter of 2004. The high volume of returns of prenatal vitamin products, due to competition from generic brands also negatively affected margins.

Research and development spending for the quarter was $1.5 million compared to $2.3 million for the same three-month period in 2003. For the year ended December 31, 2004, research and development costs were $7.4 million compared to $10.1 million in year ended December 31, 2003. The change was due to manufacturing start-up costs in 2003 being accounted for in the research and development category until April 2004. Beginning in April 2004, manufacturing costs have been included in cost of sales and inventory.

Selling and marketing expenses were $6.3 million for the three-month period ended December 31, 2004, reflecting the costs associated with launching ESTRASORB, compared to $1.7 million for the same three month period last year. For the 2004 fiscal year selling expenses were $11.0 million compared to $7.6 million in 2003. The change was primarily due to the addition of sales personnel to implement the ESTRASORB launch. Marketing expenses were $12.6 million for the 2004 fiscal year compared to $0.2 million in 2003. The increase was due to advertising and promotion costs related to the 2004 product launch of ESTRASORB.

General and administrative costs were $2.7 million for the quarter compared to $2.3 million for the same quarter in 2003. General and

administrative costs were $8.7 million in 2004 fiscal year compared to $7.9 million in 2003. The change is primarily due to increased accounting fees related to the implementation of internal control evaluation and reporting procedures as required by the Sarbanes-Oxley Act of 2002.

As of December 31, 2004, the Company had $17.9 million of cash and cash-equivalents compared to $27.6 million at December 31, 2003. In the event the Company is unable to obtain a marketing partner or raise additional finances, the Company may not have sufficient cash flows to finance the business operations in 2005 as currently contemplated.

Significant Opportunities for 2005
The transdermal estrogen therapy market represents a $250 million annual market with over 100,000 prescriptions written each week. ESTRASORB's product profile is strong, as evidenced by the response from physicians aware of the product and patient continuation rates. Partner interest in both Europe and North America remains high, with discussions ongoing.

Novavax will continue to develop its pipeline products, specifically its proprietary micellar nanoparticle (MNP) platform, a platform validated by virtue of the FDA approval of ESTRASORB in October 2003. MNP offers an attractive opportunity to capitalize on additional product development opportunities through the reformulation of approved pharmaceutical molecules in a topical delivery format. Five new products have completed the animal blood level stage of the pre-clinical tests. Once the results are evaluated by the Company will provide a market update on its clinical plan.

Conference Call
The Company will hold a conference call to discuss its results at 8:30 a.m. (EST) on March 15, 2005. The call will be hosted by Mr. Nelson M. Sims, President and CEO. Mr. Sims will be joined by other senior management to review the results. A question and answer session will follow, at which time the operator will direct participants as to the correct procedure for submitting questions. The dial in number for the conference call is 1 (800) 814-4853.

A live audio webcast of the conference call will be available through http://www.novavax.com. Please connect to this website at least 15 minutes prior to the conference call to ensure adequate time for any software download that may be needed to hear the webcast. A replay of the webcast will be available for 90 days starting on March 15, 2005 at www.novavax.com. A replay of the conference call will also be available by telephone on March 15, 2005 through March 22, 2005. To access the replay, dial 1-877-289-8525 and enter reservation number 21115589#.

About Novavax Inc.
Novavax, Inc. is a specialty biopharmaceutical company engaged in the research, development and commercialization of proprietary products focused on drug delivery and vaccine development. Novavax sells, markets, and distributes a line of women's health prescription pharmaceuticals through its specialty sales force calling on obstetricians and gynecologists throughout the United States including ESTRASORB, its topical emulsion for estrogen therapy. Novavax's micellar nanoparticle technology involves the use of patented oil and water emulsions that it believes can be used as vehicles for the topical delivery of a wide variety of drugs and other therapeutic products, including hormones. In addition, Novavax conducts research and development on preventative and therapeutic vaccines and proteins for a variety of infectious diseases, including HIV, influenza, SARS and E- selectin tolerogen for the prevention of stroke.

Statements made in this press release that state Novavax's or management's intentions, hopes, beliefs, expectations, or predictions of the future are forward-looking statements. Forward-looking statements include but are not limited to statements regarding product sales, future product development and related clinical trials and statements regarding future research and development. Novavax's actual results could differ materially from those projected in such forward-looking statements. Factors that could cause actual results to differ materially from those in the forward-looking statements include, among other things, the following: general economic and business conditions; competition; unexpected changes in technologies and technological advances; ability to commercialize and manufacture products; results of clinical studies; research and development activities; changes in, or failure to comply with, governmental regulations; and the ability to obtain adequate financing in the future. Additional information is contained in Novavax's annual report on Form 10K for the year ended December 31, 2003, and Form 10Q for the quarters ended March 31, 2004, June 30, 2004 and September 30, 2004 incorporated herein by reference. Statements made herein should be read in conjunction with Novavax's Forms 10K and 10Q. Copies of the filing may be obtained by contacting Novavax at 508 Lapp Road, Malvern, PA 19355 Tel 484-913-1200 or the SEC at www.sec.gov.

Item 9.01. Financial Statements and Exhibits.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Novavax, Inc.

March 14, 2005

By: Nelson M. Sims

Name: Nelson M. Sims
Title: President and Chief Executive Officer

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Exhibit Index

Exhibit No.	Description
99.1	Consolidated Statements of Operations